

US EPA ARCHIVE DOCUMENT

EPA Reviewer: M. Hashim

Date: May 17, 2006

Risk Manager (EPA): 25

STUDY TYPE: Acute Inhalation Toxicity –Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: SP1022 (Triclopyr-Triethylamine salt 14.8%), Lot #870IP506-2A, Gray granules

CITATION: Moore, G. (2006). Acute Inhalation Toxicity in Rats. Product Safety Laboratories, Dayton, NJ 08810, Study #: 18014 dated 9-28-05 MRID 46791905. Unpublished.

SPONSOR: SePRO Corporation, Carmel, IN 46032-4565.

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 46791905), SD rats, 5/sex (Weight: 251-271 g males; 119-201 g females) were exposed to SP1022 (Triclopyr-Triethylamine salt 14.8 at a (gravimetric) concentration of 2.04 mg/L for 4 hours. The test substance was made into a powder then aerosolized having a particle size at an av of 3.6 µm. Individual animal body weights were recorded prior to the test exposure, and then weekly weights thereafter. Behavioral changes and cage-side observations were made at least every 30 minutes during the exposure and once daily for the entire study for a 2-wk study. All animals were necropsied at the end of study.

One animal died following (30 mts. of exposure) on the study (Table 1). This animal showed hunched posture and hypoactivity in the first half hour. The remaining animals showed ocular and nasal discharge. All these animals recovered in one day. All survivors were healthy for the remaining of the study, gained normal body weight. Necropsy of the decedent showed discoloration of intestine and lungs (including edema of lung). No gross lesions were observed at necropsy for the terminal animals.

LC₅₀ Combined > 2.04 mg/L
Males > 2.04 mg/L
Females > 2.04 mg/L

Based on the combined LC₅₀ 2.04 mg/L, SP1022 is classified as EPA Toxicity Category IV for acute inhalation toxicity.

This acute inhalation study is classified as acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Table 1. Outcome of Inhalation Test

Gravimetric Conc. (mg/L)	MMAD µm	GSD	Mortality/Number Tested		
			Males	Females	Combined
2.04	3.6	1.98	1/5	0/5	1/10

Test Atmosphere / Chamber Description:

Gravimetric Conc.:	2.04 mg/L
Chamber Volume:	100 L
Airflow:	4 L/min
Temperature:	21-23 degrees C
Relative Humidity:	58-78%

Particle size determination - Particle size was determined by Anderson Cascade Impactor.

Mortality/ Clinical Signs: One animal died following (30 mts. of exposure) on the study (Table 1). This animal showed hunched posture and hypoactivity in the first half hour. The remaining animals showed ocular and nasal discharge. All these animals recovered in one day. All survivors were healthy for the remaining of the study, gained normal body weight.

Necropsy: Necropsy of the decedent showed discoloration of intestine and lungs (including edema of this organ). No gross lesions were observed at necropsy for the terminal animals.

Reviewer's Conclusions: Agree with study author that the combined inhalation LC₅₀ > 2.04 mg/L.